

EXCEPTIONS FOR THE REPROCESSING OF SINGLE USE STERILE MEDICAL DEVICES POLICY

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Reviewed: June 2023

Policy Applies to:

All Mercy staff who handle medical devices and Credentialed Specialists whom request the return of devices for teaching purpose.

This policy will be shared with external healthcare practices who utilise sterilising facilities at Mercy

Related Standards:

- AS/NZS 4187:2014. Reprocessing of reusable medical devices in health service organisations
- Ngā Paerewa Health and Disability Services Standard NZS 8134:2021
- EQuIP Standard 1. 5 Criterion 1.5.2
- EQuIP Standard 3. 2 Criterion 3.2.1

Rationale:

To ensure that there is an effective process to evaluate requests for the reprocessing of single use items in accordance with approved guidelines and standards.

Cultural Considerations:

There are no identified cultural considerations for this policy.

Definitions:

Single Use / Single patient use

A medical device which has been labelled by the manufacturer as sterile 'single use' or 'single patient use' is intended for one use on one patient only.

Reuse or Reprocess

The cleaning, inspection, packaging and sterilisation of a sterile 'single use' or 'single patient use' medical device (only for inclusions as noted below) for the intention of using on a patient.

This includes:

- re-packaging and resterilising of a sterile 'single use' or 'single patient use' medical device that has been opened but NOT used
- The re-sterilisation of an unopened sterile 'single use' or 'single patient use' medical device which has expired.

Objectives

- To identify situations where single-use items can be safely reused
- To ensure the process for the reuse of medical devices is robust and safe.



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Criteria for Reprocessing Assessment

- Single-use medical device that is to be used in a sterile manner, which has been opened but not used.
- Unopened sterile single-use medical device which has expired.

Implementation

- All requests for single-use medical device reprocessing must be made to the CSSD Coordinator
- Staff making requests are required to provide relevant supporting documentation from the manufacturer which validates the reuse and reprocessing of the single-use item
- Single use items that are reprocessed will be reported by the CSSD Coordinator to the Infection Prevention and Control Committee.

Evaluation:

- Documented manufacturer's instructions for each approved re-use item
- Tracking Record for monitoring of each approved item: kept in CSSD and archived Monthly
- Infection Prevention and Control Committee report.

Associated Documents:

Internal

- Standard Precautions Policy
- Product Evaluation Policy
- Infection Prevention and Control Committee Terms of Reference.

Acknowledgements

- CDHB Reprocessing of Single-use Medical Devices 2021
- BoPDHB Reuse of Single-use Medical Devices 2022